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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,522	10/13/1999	MICHAEL NEHLS	8535-027-999	7547

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EXAMINER
MORAN, MARJORIE A

ART UNIT	PAPER NUMBER
1631	24

DATE MAILED: 06/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/417,522	NEHLS ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3 and 5-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Arguments

In view of the appeal brief filed on 3/24/03, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

All rejections and objections not repeated below are hereby withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 101/112 Utility Rejections

Claims 3 and 5-13 are again rejected, as previously set forth in the office action of 7/17/01, under 35 U.S.C. 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

Applicant's arguments filed 3/24/03 have been fully considered but they are not persuasive.

Applicant argues on page 5 of the appeal brief that the claimed sequences may be used for physical and genetic mapping of the human an/or the genome of model organisms, or may be used as probes. In response, it is noted that a "use" for physical and genetic mapping, or as a probe are utilities generic to the broad class of polynucleotides, and are therefore not specific, substantial and credible utilities for the particular polynucleotides claimed. Applicants further argue that the claimed nucleic acids can be used for different lineages or for different stages of differentiation and development. In response, it is noted that the specification does not disclose anywhere that any of SEQ ID NO's 9-18 are know to localize to a particular gene or chromosome, are known to be differentially expressed in particular tissues, or are known to be developmentally expressed and/or to regulate any stage of development. The specification discloses, on page 75 that SEQ ID NO's 9-18 were isolated from human teratocarcinoma cells, but there is no disclosure or other evidence that the claimed sequences are specific to these cells and/or are differentially expressed in carcinoma cells in general. Applicant repeats arguments previously set forth that the putatively disrupted genes fall within a specific class which are distinct from the general broad class of genes in the genome; however, applicant again fails to specifically identify the "specific class" of genes to which the claimed polypeptides belong. Applicant argues on page 7 of the appeal brief that "every gene in the genome, when disrupted, necessarily provide the specific utility..." This appears to be an admission that ANY gene in the genome, when disrupted, would have the same utility as that argued for SEQ ID NO's 9-18. If any gene in the genome, when disrupted, would have the disclosed utilities, then

those utilities are necessarily those applicable to the broad class of genes, and are not specific, substantial and credible utilities. Applicants assert on page 8 of the appeal brief that the identified functions represent a specific class of genes involved in late stages of stem cell differentiation and development. In response, it is again noted that the instant specification does not disclose that SEQ ID NO's 9-18 are known to be involved in/regulate differentiation or development of any cell type, nor has applicant provided any evidence to support this argument. In response to arguments for what the genes are NOT, it is noted that neither the specification nor any other evidence supports that SEQ ID NO's 9-18 are known to NOT be inhibitors of cell death or apoptosis, or to NOT be involved in general housekeeping. In addition, mere knowledge or disclosure of what a gene does NOT do is not a disclosure for what the gene DOES do, or what activities it may regulate. It is again noted that the specification discloses on page 60 that the inventive sequences CAN BE used in cell-based systems to identify compounds which MAY BE involved in development and cell differentiation disorders, but does not specifically identify sequences which are associated with said disorders, nor does the specification disclose that any sequences have been identified which HAVE BEEN used in such a cell-based assay. It is noted that the specification also discloses on page 55 that the inventive sequences can also be used to identify signal transduction pathways and catalytic events, but does not specifically identify which sequences are associated with such pathways or events.

Applicant argues on page 9 of the appeal brief that the claimed sequences have a currently available utility to identify "important regulators of cell differentiation." Applicant is again reminded that a "use" to do further research (e.g. to identify a gene

which is involved in development, differentiation, signal transduction, etc.) is not considered a specific, substantial, and credible utility. As set forth above, a method of making a compound without utility does not itself have utility. The same is true for a method of use of a compound without utility. As it is not known whether any of SEQ ID NO's 9-18 are actually involved in cell differentiation, a method of identifying compounds which hydridize to SEQ ID NO's 9-18 would not confer a "currently available utility" on any of SEQ ID NO's 9-18.

For the reasons set forth above, applicant's arguments are not convincing, and the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3 and 5-13 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

Applicant's arguments filed 3/24/03 have been fully considered but they are not persuasive. Applicant argues that as the claimed sequences have utility, one would

know how to use them. In response, it is noted that while a variety of "uses" are disclosed by the instant specification, the specification does not actually disclose how to use any of SEQ ID NO's 9-18 in particular. The state of the prior art is such that it is known how to perform general hybridization experiments; e.g. to compare sequences to detect a polymorphism, how to perform subtractive assays to find sequences specific to a particular tissue, etc. However, as neither the specification nor the prior art discloses that any of SEQ ID NO's 9-18 are known to comprise a polymorphism, or are known to be associated with a disease or disorder, such that hydridization would be useful, it would require undue experimentation by one skilled in the art to determine how to use the claimed sequences to detect a polymorphism or to diagnose or detect a disease or disorder. Neither the specification nor the prior art teach that any of SEQ ID NO's 9-18 are known to be specific to a particular tissue, cell type, developmental stage, or to be involved in differentiation, therefore it would require undue experimentation to determine how to use the claimed sequences in assays to detect, follow, etc. development and/or differentiation of cells and tissues. The level of skill in the art is acknowledged to be high, however, given the lack of teaching is either the specification or the prior for specific assays in which SEQ ID NO's 9-18 are known to be useful, it would require undue experimentation for one skilled in the art to know how to use the claimed sequences.

Claim Rejections - 35 USC ' 112

Claims 3 and 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a WRITTEN DESCRIPTION rejection.

Applicant's arguments filed 3/24/03 have been fully considered but they are not persuasive. Applicant again argues that the claimed sequences are identified by structure/formula (i.e. sequence) and/or by functional property (i.e. ability to hybridize to certain sequences under particular conditions). Applicant further argues that the specification discloses exemplary elements which may be included in the claimed polynucleotides, and that one skilled in the art can readily isolate and distinguish polypeptides with the claimed hybridization properties recited in claim 13. In response, it is noted that a large variety of noncoding regions, regulatory sequences, and vector sequences are known in the art, and are not described in the instant specification. In addition, since the claims recite open language, the claimed polynucleotides may comprise repetitive sequences, and, potentially, entire genes or coding regions not disclosed by the instant specification. It is also noted that the fact that one skilled in the art can identify and distinguish polypeptides based on hybridization properties does not constitute a written description of the polypeptide, sequence, structure, etc. so identified.

For these reasons and those previously set forth, the examiner maintains that none of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims, therefore the rejection is maintained.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

Isolated polynucleotides comprising a contiguous stretch of "at least about 30 nucleotides", "at least about 40 nucleotides", and "at least about 40 nucleotides capable of hybridizing...." are new matter. The originally filed specification teaches on page 4 that oligonucleotides may comprise "at least about" 50, 75, 100, or 130 nucleotides. Page 4 does not disclose that the sequences are contiguous. The originally filed specification also teaches, on page 16, that inventive sequences may comprise contiguous stretches of "at least" 30, 40, or 60 nucleotides. Page 16 does not teach a contiguous stretch of "at least about" any length of nucleotides. Original claim 1 recited a polynucleotide comprising "at least about 15" nucleotides and original claim 3 recited "at least about 60" nucleotides. None of the original claims recited a sequence comprising a contiguous stretch of "at least about 30" or "at least about 40" nucleotides. Claims 10-11 and 13 are not original claims. As neither the originally filed

specification or claims provide support for a polynucleotide comprising "at least about 30" or "at least about 40" nucleotides, claims 10-11 and 13 recite new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by HILLIER et al. (NCBI accession number R91187).

HILLIER teaches a polynucleotide sequence comprising a contiguous stretch of 35 nucleotides which are identical to residues 6-40 of instant SEQ ID NO: 12, thereby anticipating claim 11.

Conclusion

Claims 3 and 5-13 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4242 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3524.

MARJORIE MORAN
PATENT EXAMINER

mam
June 13, 2003